

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

CHRISTOPHER MCNAUGHTON, a
Pennsylvania citizen,

Plaintiff,

vs.

UNITEDHEALTHCARE INSURANCE
COMPANY, a Connecticut corporation,
UNITED HEALTHCARE, INC., a
Delaware corporation,

Defendants.

CIVIL ACTION

Case No.: 2:21-cv-03802

**PLAINTIFF’S BRIEF IN SUPPORT OF MOTION FOR TEMPORARY
RESTRAINING ORDER, PRELIMINARY INJUNCTION AND
EXPEDITED HEARING**

I. STATEMENT OF FACTS

Plaintiff Christopher McNaughton is in immediate and dire need of medically necessary medications in specific dosages that defendant, United Healthcare Insurance Company and United Healthcare, Inc. (“United”) have denied. (Declaration of Christopher McNaughton (“McNaughton Dec.”), paras. 7-10 and Declaration of Dr. Edward Loftus (“Loftus Dec.”), paras. 10-14.) McNaughton cannot afford these prescriptions without United’s coverage because they cost over \$150,000 per month. (McNaughton Dec., para. 11.) Absent this

Court's issuance of an injunction, McNaughton will miss his prescribed treatment causing a significant risk of danger to his health, including potentially permanent and life-threatening consequences. (Loftus Dec., paras. 10-14.)

McNaughton suffers from severe ulcerative colitis. (Loftus Dec., paras. 2, 10-14.) This disease causes McNaughton to have bloody diarrhea up to twenty times a day; severe abdominal pain; severe anemia causing constant fatigue; loss of appetite; significant weight loss and malnutrition; severe inflammatory arthritis which leaves him unable to walk and requiring hospitalization; severe, recurrent, life-threatening, deep vein thrombosis resulting in repeated hospitalizations; repeated fractures and osteopenia; and severe secondary adrenal insufficiency. (Loftus Dec. para. 2.)

McNaughton was referred to Dr. Edward Loftus at the Mayo Clinic in May 2015 due to the severity of his ulcerative colitis. (Loftus Dec., para. 3.) In October 2018, after failing numerous other treatment options and doses, Dr. Loftus prescribed McNaughton Remicade 20 mg/kg every 4 weeks and Entyvio 600 mg every 4 weeks. (Loftus Dec., paras. 4, 10-14.) Both those medications are medically necessary for McNaughton. (Loftus Dec., paras. 1-15.)

The medication prescribed by Dr. Loftus was initially covered by McNaughton's former health insurer, Aetna, before McNaughton subscribed to United's health plan at Penn State. (McNaughton Dec., para. 4.) Then United

covered it from July 1, 2020 to August 12, 2021 after United contracted to provide McNaughton with medically necessary health care in exchange for monthly premium payments. (McNaughton Dec., paras. 4 and 13.)

Under this plan, United agreed to pay “for Covered Medical Expenses . . . less any deductible incurred by or for an insured Person for loss due to injury or sickness subject to: a) the maximum amount for specific services as set forth in the Schedule of Benefits; and b) any Coinsurance or Copayment amounts set forth in the schedule of Benefits or any benefit provision hereto.” Covered Medical Expenses include infusion therapy and prescription drugs.

The plan defines “Covered Medical Expenses” as “reasonable charges which are: 1) not in excess of Usual and Customary Charges; 2) not in excess of the Preferred Allowance when the policy includes Preferred Provider benefits and the charges are received from a Preferred Provider; 3) not in excess of the maximum benefit amount payable per service as specified in the schedule of benefits; 4) made for services and supplies not excluded under the policy; 5) made for services and supplies which are a medical necessity; 6) made for services included in the Schedule of Benefits and 7) in excess of the amount stated as a deductible, if any.”

Medical necessity and medically necessary are defined in the policy as follows: “those services or supplies provided or prescribed by a Hospital or

Physician which are all of the following: 1) Essential for the symptoms and diagnosis or treatment of the Sickness or Injury; 2) Provided for the diagnosis, or the direct care and treatment of the Sickness or Injury; 3) In accordance with the standards of good medical practice; 4) Not primarily for the convenience of the Insured, or the Insured's Physician; 5) The most appropriate supply or level of service which can safely be provided to the Insured."

On May 14, 2021, McNaughton received a denial email indicating that United would not cover his infusions at the prescribed doses for the 2021-22 plan year. The email said that the reason for the denial was that, in the peer-to-peer review, Dr. Loftus had agreed that the current treatment was "not appropriate." Dr. Loftus has indicated in writing that the statements, which form the basis of United's denial, are false. (Loftus Dec., paras. 5, 7.)

On May 19, 2021, Dr. Loftus wrote a letter stating that McNaughton required the treatments that he prescribed, and that failure to provide these treatments could have "serious detrimental effects on both his short term and long term health and could potentially involve life threatening complications." (Loftus Dec., para. 6.) "McNaughton was on the doses suggested by United Healthcare before, and they were not at all effective." (*Id.*, Attached as Exhibit 2 to the Loftus Dec. is the May 19, 2021 letter.)

On June 4, 2021, after being confronted with the false statements in their May 14, 2021 email, United sent another denial letter to McNaughton advising him that it would not cover his treatments. (McNaughton Dec., para. 6, Attached as Exhibit 3 to the Loftus Dec. is the June 4, 2021 denial letter.) Prior to the June 4, 2021 letter, Dr. Loftus had explained that McNaughton would suffer “serious”, “long term”, and “life threatening complications” if United did not provide coverage for the treatments. (Loftus Dec., para. 6.)

On June 7, 2021, Dr. Loftus wrote another letter explaining that United’s prior communications regarding Dr. Loftus were inaccurate. (Loftus Dec., para. 9, Exhibit 4, June 7, 2021 letter). Dr. Loftus did not say the things attributed to him that formed the basis of the United denial as represented in Dave Opperman’s email to McNaughton dated May 14, 2021. *Id.*

As noted above, McNaughton has been treated by Dr. Loftus at the Mayo Clinic for the past 6 years. (Loftus Dec., para. 10.) McNaughton’s disease is severe and difficult to treat. *Id.*

McNaughton has a 7-year history of severe refractory ulcerative colitis, and he had been steroid-dependent despite multiple medications. (Loftus Dec., para. 11.) He is currently on an intensive regimen of Entyvio, Remicade, azathioprine, allopurinol, mesalamine suppositories, and budesonide foam. *Id.* With this regimen, McNaughton is in clinical remission from his ulcerative colitis. *Id.*

Prior to beginning his current treatment regimen, McNaughton was hospitalized numerous times with what had the potential to be life-threatening complications. *Id.* If McNaughton's treatment were interrupted or delayed in any way by United's actions, he would be at substantial risk for loss of response to his current protocol, placing his health in significant danger. *Id.* Remicade and Entyvio are biologic medications. He cannot just stop and restart or reduce doses, as there is a high likelihood they would no longer be effective. *Id.* This is especially problematic for McNaughton, as he has failed numerous other ulcerative colitis medications, and endured significant suffering over 5 years before arriving at his current protocol. *Id.* If McNaughton were to have his current treatment protocol interrupted, it might stop being effective, endangering McNaughton's life. *Id.*

It is Dr. Loftus's expert medical opinion that McNaughton continue with his current treatment regimen of Remicade 20mg/kg every 4 weeks and Entyvio 600 mg every 4 weeks. (Loftus Dec., para. 12.) The combination has been crucial in allowing him to finally taper off high dose prednisone after 5 years and avoid the substantial side effects that come with long term prednisone use. *Id.* This treatment protocol has helped McNaughton to achieve and maintain his current level of health and avoid frequent and recurring hospitalizations as well as extraintestinal manifestations. *Id.* The combination of Remicade 20 mg/kg every 4 weeks and

Entyvio 600 mg every 4 weeks was arrived upon after McNaughton failed numerous other treatments over a 5-year period. *Id.*

If McNaughton were to follow the regimen suggested by United in the email dated May 14, 2021 (Remicade 5 mg/kg every 8 weeks and Entyvio 300 mg every 8 weeks), it would have serious detrimental effects on both his short term and long term health and could potentially involve life-threatening complications. *Id.* McNaughton was on the doses suggested by United Healthcare before, and they were not at all effective. *Id.*

McNaughton has failed all lower doses and combinations of these medications, so it is essential that he receive them at the doses they are currently prescribed (Entyvio 600 mg every 4 weeks and Remicade 20mg/kg every 4 weeks). (Loftus Dec., para. 13.) As a result, it is Dr. Loftus' medical opinion that McNaughton continue with his current treatment regimen. *Id.*

As stated in Dr. Loftus's letters on the subject, if McNaughton does not get these treatments as scheduled it could have serious and significant adverse consequences to his health. (Loftus Dec., paras. 10-14.) The treatment is medically necessary and is neither experimental nor investigational.

McNaughton's next scheduled treatment is on September 10, 2021 for Entyvio and on September 24, 2021 for Remicade, but since United already denied coverage for these infusions, he will almost certainly be unable to receive the

treatment as scheduled unless this Court orders United to pay for the treatment. (McNaughton Dec., para. 13.) Failure to obtain the treatment as scheduled will probably result in serious detrimental effects on both his short term and long term health and potentially life-threatening consequences to McNaughton. (Loftus Dec., paras. 10-14.)

II. THE COURT SHOULD GRANT THE PRELIMINARY INJUNCTION

Federal Rule of Civil Procedure Rule 65 (“Rule 65”) states, in relevant part:

(a) PRELIMINARY INJUNCTION.

(1) *Notice*. The court may issue a preliminary injunction only on notice to the adverse party.

(2) *Consolidating the Hearing with the Trial on the Merits*. Before or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing. Even when consolidation is not ordered, evidence that is received on the motion and that would be admissible at trial becomes part of the trial record and need not be repeated at trial. But the court must preserve any party's right to a jury trial.

Rule 65(a) of the Federal Rules of Civil Procedure provides that courts have the discretion to issue a preliminary injunction after affording the adverse party notice.

Hynoski v. Columbia Cty. Redevelopment Auth., 485 F. App'x 559 (3d Cir. 2012);

Bradley v. Pittsburgh Bd. of Educ., 910 F.2d 1172, 1175-76 (3d Cir. 1990).

The general standard for preliminary injunctive relief is not a rigid test.

Constructors Ass'n of Western Pennsylvania v. Kreps, 573 F.2d 811, 815 (3d Cir.

1978). There are four factors that are to be balanced to guide the Court's discretion,

with no one factor being necessarily determinative. *Id.* The party seeking a preliminary injunction must clearly carry the burden of persuasion on each of four elements, which are as follows:

(1) a substantial likelihood that he will prevail on the merits, (2) a substantial threat that he will suffer irreparable injury if the injunction is not granted, (3) his threatened injury outweighs the threatened harm to the party whom he seeks to enjoin, and (4) granting the preliminary injunction will not disserve the public interest.

Id.; see also *ACLU of New Jersey v. Black Horse Pike Regional Board of Education*, 84 F.3d 1471, 1477 n.2 (3d Cir. 1996)(*en banc*); *E. R. Squibb & Sons, Inc. v. Hollister, Inc.*, 1991 U.S. Dist. LEXIS 1395 at *4-5 (D.N.J. 1991)(*citing Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 800 (3d Cir. 1989)); *Lake Charles Diesel, Inc. v. GMC*, 328 F.3d 192, 195 (5th Cir.2003) (*quoting Mississippi Power & Light Co.*, 760 F.2d at 621); *Chambers v. Coventry Health Care of La., Inc.*, 318 F. Supp. 2d 382 (E.D. La. 2004).

It is established law that courts may issue injunctions to compel the payment of health benefits. See *Adams v. Freedom Forge Corp.*, 204 F.3d 475 (3d Cir. 2000). As stated above, Rule 65(a) of the Federal Rules of Civil Procedure authorizes the district courts to issue a preliminary injunction in order to protect a plaintiff from irreparable injury and to preserve judicial power to render a decision after trial on the merits. *Canal Authority v. Callaway*, 489 F.2d 567, 572 (5th Cir.1974). “The grant or denial of a preliminary injunction rests in the discretion of

the district court.” *Id.* Although the federal rules authorize the use of a preliminary injunction, it remains an “extraordinary remedy,” and a court’s decision to grant preliminary injunctive relief is “the exception rather than the rule.” *Karaha Bodas Co. v. Negara*, 335 F.3d 357, 363-64 (5th Cir.2003) (quoting *Mississippi Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir.1985)).

The order sought by McNaughton in this case is similar in many respects to the Rule 65 order issued in Chambers where the plaintiff was diagnosed with cancer. Mr. Chambers underwent surgery, but that surgery was not successful. *Id.* at 385. Plaintiff began a course of chemotherapy and was treated by Dr. William Stein. *Id.* On March 5, 2004, Dr. Stein requested authorization from Defendant Coventry Health Care of Louisiana, the Plaintiff’s health insurance provider, to perform a PET fusion scan. *Id.* The request was denied. *Id.* On March 30, 2004, Dr. Stein again requested authorization from the Defendant to perform the PET fusion scan, and the Defendant again denied the request. *Id.*

In *Chambers*, Plaintiff brought suit against Coventry seeking a temporary restraining order, preliminary injunction, and permanent injunction. *Id.* at 386. Specifically, he sought to prohibit the Defendant from enforcing its decision to deny the treatment under the health plan purchased by the Plaintiff. *Id.* The Court issued a preliminary injunction forcing the insurer to pay for the next treatment sought. *Id.* at 392.

A. McNaughton Risks Substantial Threat of Irreparable Injury

To receive preliminary injunctive relief, an applicant must show by credible evidence that the failure to issue injunctive relief poses an actual threat of an injury that cannot be adequately compensated through the normal litigation process. *Id.* at 388-389. As in *Chambers*, McNaughton claims that he will suffer irreparable injury from his insurer's refusal to authorize the medically necessary treatment. *Id.* McNaughton has a debilitating disease. His treating physician testifies that he will suffer serious detrimental effects on both his short term and long term health and potentially life-threatening consequences if he does not receive treatment in a timely manner. Moreover, these consequences could be permanent. This is the definition of irreparable harm.

Although the cost is prohibitive to McNaughton, \$150,000 per month is insignificant to United. As with the Plaintiff in *Chambers*, there is no question that McNaughton cannot afford the payment and United certainly can. *Id.*

B. Balance of Potential Harms Easily Favors McNaughton

The potential harm to McNaughton from not granting the preliminary injunction clearly outweighs any harm to United from issuing the injunction. McNaughton is a college student who suffers from ulcerative colitis that is debilitating when not controlled by the prescribed medications and doses sought. United is a division of a national insurance company with more than 45,000,000

members.¹ United profited \$15.4 billion in 2020. The life-threatening and permanent injuries that could result from McNaughton's failure to obtain the medication on schedule easily outweighs the possible \$150,000 per month harm to United.

C. The Public's Interest is Not Harmed

The grant of this preliminary injunction would not harm the public in any way. The dispute arises between an individual and a corporation. In this motion for preliminary injunction, McNaughton seeks an injunction that relates only to the provision of two particular doses of medication. He is currently only seeking the Court's ruling with respect to his own treatment.

D. McNaughton Will Likely Succeed on the Merits

Finally, McNaughton demonstrates a substantial likelihood that he will be successful on the merits to obtain preliminary injunctive relief. In the context of a request for a preliminary injunction, the plaintiff need not demonstrate an absolute certainty of success on the merits. *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C.Cir.1977). It is enough that the plaintiff raises legal questions that are sufficiently serious and substantial that a more thorough investigation is appropriate. *Chambers at* 390-391.

¹ <https://www.uhcmedicareolutions.com/about-us.html#:~:text=Globally%2C%20UnitedHealthcare%20serves%20more%20than,a%20diversified%20health%20care%20company>

The Court need not decide whether or not the treatment sought is covered under the terms of the McNaughton's plan. *Chambers* at 391. That decision can await a trial on the merits. *Id.* The evidence produced by McNaughton is sufficient to raise legal questions that are sufficiently serious and substantial so that a more thorough investigation is appropriate. This satisfies the likelihood of success required by Rule 65(a). *Id.*

III. CONCLUSION

For all of the above-stated reasons, this Honorable Court should find that there is a substantial likelihood that McNaughton will prevail on the merits, that there is a substantial threat that he will suffer irreparable injury if the injunction is not granted, and that his threatened injury outweighs the threatened harm to United whom he seeks to enjoin. Further, the Court should find that granting of the preliminary injunction will not disserve the public interest. Further, the Court should grant McNaughton's Motion for Temporary Restraining Order, Preliminary Injunction and Expedited Hearing and issue the proposed Order submitted by McNaughton.

DATED: September 20, 2021 **MUNLEY LAW, PC**

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